

## **REMARKS**

The examiner has requested an election of species with respect to two issues. The applicant intends to elect each species *with traverse*. Specifically, in response to the first election of species requirement, the applicant elects the LOX-1 receptor, with traverse. Arguments against the allegation of lack of unity are below. Claims 1, 4, 10 and 14-21 are readable onto this elected species. In response to the second election of species requirement, the applicant elects, with traverse, the method identified by the examiner as ‘species (c)’ as defined by claims 16 and 17, that is, methods that comprise measuring receptor binding of CEL to cells expressing the receptor on their surface. Arguments against the allegation of lack of unity are below. Claims 1, 4, 10-13, 16 and 17 are readable onto this elected species.

### **A. Arguments Against Alleged Lack of Unity**

#### *1. First Election of Species*

The examiner alleges that the claims are “directed to more than one species of receptor of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.” The examiner identifies the following species of receptor:

Glycosaminoglycan, heparin, heparin sulfate, chondroitin-6-sulphate, chondroitin-4-sulphate, dermatan sulphate, SR-A type I, SR-A type II, SR-A type III, MARCO, SR-BI, CD36, SR-CI, SR-D, Macrosialin/CD86, SR-E, LOX-1, SR-F, SREC-1, SR-PSOX, FEEL-1, FEEL-2, RAGE, 80K-H, OST48, Galectin-3, LPL (lipoprotein lipase), apo A-I, apo A-II, apo B-100, apo B-48, apo C-I, apo C-II, apo C-III, apo E, VLDL1, VLDL2, VLDL3, IDL1 IDL2, IDL3, LDL1, LDL2, LDL3, pre $\beta$ -HDL,  $\alpha$ -HDL, HDL1, HDL2, HDL3, and chylomicrons.

According to the examiner, “The species listed above do not relate to a single general inventive concept under Rule 13.1 PCT because, under Rule 13.2 PCT, the species lack the same or corresponding special technical features for the following reasons: each species of receptor is a distinct protein (or assembly of protein and lipid) with different molecular structure imparted by the unique sequence of amino acids (and optionally, combination with lipid molecules). Lack of unity is shown because these molecules lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.” The applicant respectfully disagrees with the examiner, and submits that the claimed receptors share a unifying feature.

The identified species do in fact possess a common utility which is based upon a common structural feature which has been identified as the basis for that common utility. All of these receptors have been defined as those that can be bound by CEL when acting as a bridging molecule. Since they can be all bound by CEL, they must all possess a common structural element, namely a CEL binding site. These represent the common utility and common structural feature requested by the examiner to demonstrate unity. Additionally, applicant notes that Rule 13.2 PCT, as cited by the examiner, reads:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only where there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.”

The different receptors listed by the examiner are all capable of binding CEL, and furthermore must all therefore possess a CEL binding site. Thus, it is clear that the listed receptors have a “technical relationship involving one or more of the same or corresponding special technical features” as required for unity by Rule 13.2 PCT. Applicant also points to MPEP § 803.02:

The members of the Markush group (A, B, and C in the example above) ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group *occurs in a claim reciting a process* or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to *possess at least one property in common* which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property.

(emphasis added). In the present case, the claims are directed to *a process* that defines a Markush group of receptor types, and since they all bind CEL and so must also possess a CEL binding site, then they must all possess “at least one property in common which is mainly responsible for their function in the claimed relationship,” that is, the ability to bind to CEL, and accordingly, “it is clear from their very nature that all of them possess this property,” as required by MPEP § 803.02.

## 2. *Second Election of Species*

The examiner alleges that the claims are “directed to more than one species of means of measuring receptor binding by CEL of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.” The examiner identifies the following species of means of measuring receptor binding by CEL:

- (a) chromatographic methods with CEL as stationary phase, as defined by Claim 14;
- (b) chromatographic methods with receptor as stationary phase, as defined by Claim 15;
- (c) measuring binding of CEL to cells expressing the receptor on their surface, as defined by Claims 16 and 17;
- (d) using scintillation proximity and ultracentrifugation, as defined by Claims 18 and 19; and
- (e) measuring binding of CEL to vascular tissue, as defined by Claims 20 and 21.

According to the examiner, “The species listed above do not relate to a single general inventive concept under Rule 13.1 PCT because, under Rule 13.2 PCT, the species lack the same or

corresponding special technical features for the following reasons: each means of measuring receptor binding is a different process for measuring affinity. Lack of unity is shown because these means of measuring receptor binding lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.” The applicant respectfully disagrees with the examiner, and submits that the claimed means of measuring receptor binding are unitary.

The identified means of measuring receptor binding do in fact possess a common utility, namely that they are used to establish the extent of binding of CEL to a receptor. Rule 13.2 PCT, as cited by the examiner, reads:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only where there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Thus, contrary to the examiner’s suggestion that “a common structural feature” is required to demonstrate unity, applicant notes that the Rule 13.2 PCT does not make any mention of the need for a common structure. Rather, Rule 13.2 PCT requires the presence of a technical relationship involving one or more of the same or corresponding special technical features, but there is no indication or suggestion that special technical features must share an identical common structure. Again, MPEP § 803.02 (see above) indicates that such is not required. All that is required is that the identified means of measuring receptor binding do in fact possess a common special technical features, namely, that they are all used to establish the extent of binding of CEL to a receptor. Accordingly, the identified means of measuring receptor binding satisfy the requirements of Rule 13.2 PCT for unity.

Additionally, insofar as means of measuring receptor binding to CEL are concerned, claim 1 is truly a generic claim, in that in its broadest sense it covers any and all means of measuring receptor binding to CEL. Therefore, the Markush practice requirement for a common structural feature would not even apply here. As such, no aspect of the controlling law supports the examiner's contention that a common *structural* feature is required to support unity for these process features.

**B. Conclusion**

Reconsideration of the restriction requirement, as set forth in the previous communication, is therefore requested.

Respectfully submitted,



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Date: November 23, 2010